



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1431.51
True Name	Coccidiosis Vaccine, Live Oocysts
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 2019

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Eimeria acervulina</i>
<b>Study Purpose</b>	Demonstrate efficacy against <i>Eimeria acervulina</i>
<b>Product Administration</b>	Coarse spray
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	November 27, 2006

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Eimeria maxima</i>
<b>Study Purpose</b>	Demonstrate efficacy against <i>Eimeria maxima</i>
<b>Product Administration</b>	Coarse spray
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	November 27, 2006

<b>Study Type</b>	Efficacy																																								
<b>Pertaining to</b>	<i>Eimeria tenella</i>																																								
<b>Study Purpose</b>	Demonstrate efficacy against <i>Eimeria tenella</i>																																								
<b>Product Administration</b>	One dose via coarse spray																																								
<b>Study Animals</b>	Chickens at day of age  Group 1 :Vaccinated, challenged:44 Group 3 : Vaccinated, non-challenged: 45 Group 5: Non-vaccinated challenged controls:44 Group 6: Non-vaccinated, non-challenged controls:14																																								
<b>Challenge Description</b>	Challenged with <i>Eimeria tenella</i> on Day 28 of study																																								
<b>Interval observed after challenge</b>	Birds were observed for 6 days and on Study Day 34, all birds in all groups were euthanized and intestinal lesions were scored.																																								
<b>Results</b>	<p>Birds with lesion scores<sup>1</sup> less than or equal to 1 were not considered to be affected with the disease and birds with scores greater than or equal to 2 were considered to be affected with the disease.</p> <p><b>Summary of affected birds</b>  Group 1 : 1/44  Group 3 : 0/45  Group 5: 35/44  Group 6: 0/14</p> <table border="1"> <thead> <tr> <th rowspan="2">Group</th> <th colspan="5">Number of Birds by Lesion Score Category</th> <th rowspan="2">Total birds</th> </tr> <tr> <th>0</th> <th>1</th> <th>2</th> <th>3</th> <th>4</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>38</td> <td>5</td> <td>1</td> <td>0</td> <td>0</td> <td>44</td> </tr> <tr> <td>3</td> <td>44</td> <td>1</td> <td>0</td> <td>0</td> <td>0</td> <td>45</td> </tr> <tr> <td>5</td> <td>3</td> <td>6</td> <td>21</td> <td>14</td> <td>0</td> <td>44</td> </tr> <tr> <td>6</td> <td>14</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>14</td> </tr> </tbody> </table> <p><sup>1</sup>Scoring was in accordance with the Johnson and Reid coccidial scoring system, as described in Experimental Parasitology, Vol. 28, P. 30-36, 1970.</p> <p>Raw data on attached page for birds with lesions <math>\geq 1</math>.</p>	Group	Number of Birds by Lesion Score Category					Total birds	0	1	2	3	4	1	38	5	1	0	0	44	3	44	1	0	0	0	45	5	3	6	21	14	0	44	6	14	0	0	0	0	14
Group	Number of Birds by Lesion Score Category					Total birds																																			
	0	1	2	3	4																																				
1	38	5	1	0	0	44																																			
3	44	1	0	0	0	45																																			
5	3	6	21	14	0	44																																			
6	14	0	0	0	0	14																																			
<b>USDA Approval Date</b>	August 7, 2007																																								

**Individual bird intestinal lesion scoring<sup>1</sup>  
data of birds with lesions**

Group	Unit	Bird	Lesion Score	Affected by <i>E. tenella</i>
1	30	3	1	No
		4	1	No
		6	1	No
	31	1	1	No
		4	2	Yes
	32	8	1	No
3	28	12	1	No
5	13	1	2	Yes
		3	3	Yes
		4	1	No
		5	2	Yes
		6	1	No
		7	2	Yes
		8	3	Yes
		9	1	No
		10	3	Yes
		11	3	Yes
		12	1	No
		13	2	Yes
		14	2	Yes
		14	2	3
	3		1	No
	4		2	Yes
	5		3	Yes
	6		3	Yes
	7		2	Yes
	8		3	Yes
	9		3	Yes
	10		2	Yes
	11		2	Yes
	13		3	Yes
	15	1	2	Yes
		2	2	Yes
		3	2	Yes
		4	2	Yes
		5	3	Yes
		6	2	Yes
		7	3	Yes
		8	2	Yes
		9	2	Yes
		10	2	Yes
		11	2	Yes
		12	2	Yes
		13	1	No
		14	3	Yes
	15	2	Yes	

<sup>1</sup>Scoring was in accordance with the Johnson and Reid coccidial scoring system, as described in Experimental Parasitology, Vol. 28, P. 30-36, 1970.

Score	Lesion Description
0	None
1	Mild lesions
2	Moderate lesions
3	Severe lesions
4	Extremely severe lesions or death

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under field conditions
<b>Product Administration</b>	Coarse spray
<b>Study Animals</b>	Chickens at day of age
<b>Challenge Description</b>	Not applicable
<b>Interval observed after challenge</b>	Mortality was recorded three weeks (21-25 days) after vaccination. A subset of birds were selected at random from the test (vaccinate) and control houses for necropsy and examination of the gut and ceca for lesions of coccidiosis.
<b>Results</b>	Please see attached page for data summary.
<b>USDA Approval Date</b>	March 20, 2008

**Table 1: Total and House Mortality for Control and Test Farms at Three Weeks-of-Age**

Study site		Control House			Test (Vaccinate) House		
	House	Mortality	Total # birds	% Mortality	Mortality	Total # birds	% Mortality
<b>Farm 1</b>	<b>1</b>	336	27100	1.24%	227	21400	1.06%
	<b>2</b>	454	27100	1.68%	266	21400	1.24%
	<b>3</b>	274	27100	1.01%	239	21400	1.12%
	<b>4</b>	296	27100	1.09%	234	21400	1.09%
	<b>5</b>	-	-	-	257	21400	1.20%
	<b>6</b>	-	-	-	165	21400	0.77%
<b>TOTAL</b>		<b>1360</b>	<b>108400</b>	<b>1.26%</b>	<b>1388</b>	<b>128400</b>	<b>1.08%</b>
<b>Farm 2</b>	<b>1</b>	417	15303	2.72%	605	15276	3.96%
	<b>2</b>	464	15392	3.01%	485	15137	3.20%
	<b>3</b>	353	15076	2.34%	566	14850	3.81%
	<b>4</b>	507	14986	3.38%	305	13346	2.29%
	<b>5</b>	300	14980	2.00%	-	-	-
	<b>6</b>	237	15027	1.58%	-	-	-
<b>TOTAL</b>		<b>2278</b>	<b>90764</b>	<b>2.51%</b>	<b>1961</b>	<b>58609</b>	<b>3.35%</b>
<b>Farm 3</b>	<b>1</b>	619	21000	2.95%	407	21000	1.94%
	<b>2</b>	681	21000	3.24%	534	21000	2.54%
	<b>3</b>	681	21000	3.24%	549	21100	2.60%
	<b>4</b>	765	21000	3.64%	585	21100	2.77%
	<b>5</b>	-	-	-	728	21100	3.45%
	<b>6</b>	-	-	-	839	21150	3.97%
<b>TOTAL</b>		<b>2746</b>	<b>84000</b>	<b>3.27%</b>	<b>3642</b>	<b>126450</b>	<b>2.88%</b>

**Table 2: Coccidiosis lesion scores\* of the intestinal tract for *Eimeria* species**

Company Name		<i>E. acervulina</i>					<i>E. maxima</i>					<i>E. tenella</i>				
	House <sup>1</sup>	Lesion Scores														
	C/T	0	1	2	3	4	0	1	2	3	4	0	1	2	3	4
Farm 1	1	6/6 <sup>2</sup>	-	-	-	-	6/6	-	-	-	-	6/6	-	-	-	-
	2	†/6	-	-	-	-	†/6	-	-	-	-	†/6	-	-	-	-
	3	6/6	-	-	-	-	6/6	-	-	-	-	6/6	-	-	-	-
	4	†/†	-	-	-	-	†/†	-	-	-	-	†/†	-	-	-	-
	5	‡/†	-	-	-	-	‡/†	-	-	-	-	‡/†	-	-	-	-
	6	‡/†	-	-	-	-	‡/†	-	-	-	-	‡/†	-	-	-	-
<b>Total</b>		<b>12/18</b>	-	-	-	-	<b>12/18</b>	-	-	-	-	<b>12/18</b>	-	-	-	-
Farm 2	1	6/6	-	-	-	-	6/6	-	-	-	-	6/6	-	-	-	-
	2	5/5	0/1	1/0	-	-	5/6	-	-	1/0	-	2/6	4/0	-	-	-
	3	6/5	0/1	-	-	-	6/6	-	-	-	-	4/6	2/0	-	-	-
	4	6/6	-	-	-	-	6/6	-	-	-	-	4/6	2/0	-	-	-
	5	6/‡	-	-	-	-	6/‡	-	-	-	-	5/‡	1/‡	-	-	-
	6	0/‡	5/‡	1/‡	-	-	6/‡	-	-	-	-	6/‡	-	-	-	-
<b>Total</b>		<b>29/22</b>	<b>5/2</b>	<b>2/0</b>	-	-	<b>35/24</b>	-	-	<b>1/0</b>	-	<b>27/24</b>	<b>9/0</b>	-	-	-
Farm 3	1	6/6	-	-	-	-	6/6	-	-	-	-	6/6	-	-	-	-
	2	6/6	-	-	-	-	6/6	-	-	-	-	6/6	-	-	-	-
	3	6/6	-	-	-	-	6/6	-	-	-	-	6/6	-	-	-	-
	4	6/6	-	-	-	-	6/6	-	-	-	-	6/6	-	-	-	-
	5	‡/6	-	-	-	-	‡/6	-	-	-	-	‡/6	-	-	-	-
	6	‡/6	-	-	-	-	‡/6	-	-	-	-	‡/6	-	-	-	-
<b>Total</b>		<b>24/36</b>	-	-	-	-	<b>24/36</b>	-	-	-	-	<b>24/36</b>	-	-	-	-

\*Birds with lesion scores less than or equal to 1 were not considered to be affected with the disease and birds with scores greater than or equal to 2 were considered to be affected with the disease. Note at Farm 1 there were a few birds noted by the investigator to have *E. acervulina* scores of 1, however since these are considered normal for this age they were not recorded.

Scoring was in accordance with the Johnson and Reid coccidial scoring system, as described in Experimental Parasitology, Vol. 28, P. 30-36, 1970.

Score	Lesion Description
0	None
1	Mild lesions
2	Moderate lesions
3	Severe lesions
4	Extremely severe lesions or death

<sup>1</sup>House C/T=Control House/Test House.

<sup>2</sup>Number of birds necropsied per Control or Test House.

†Birds were not necropsied in one or more of the Control or Test Houses. Birds were not necropsied in these houses because the licensee investigator considered it was not necessary due to the health status and uniformity of the flocks.

‡There were four controls houses at Farms 1 and 3, and four test houses at Farm 2.